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Bio-Path Holdings Provides Update from Phase 1/1b Clinical Trial of BP1002 for Treatment of Refractory/Relapsed Acute Myeloid Leukemia

Study Progresses to Fourth Higher 90 mg/m^2 Dose Cohort

Compelling Patient Response Highlighted by Stable Disease and Significant Reduction in Blast Count After One Treatment Cycle

HOUSTON – February 12, 2025 – Bio-Path Holdings, Inc., (NASDAQ:BPTH), a biotechnology company leveraging its proprietary DNAbilize® liposomal delivery and antisense technology to develop a portfolio of targeted nucleic acid cancer and obesity drugs, today provides an update from the Company's ongoing Phase 1/1b clinical trial evaluating BP1002 for the treatment of refractory/relapsed acute myeloid leukemia (AML), including venetoclax-resistant patients. The Company announced a meaningful patient response to treatment and the clinical trial has progressed to the fourth, higher dose cohort of 90 mg/m^2.

"We were excited to learn that one patient in the third cohort had a meaningful response to just one treatment cycle, experiencing stable disease and a significant reduction in blast count, which we believe offers promise for venetoclax-resistant AML patients with limited treatment options," said Peter Nielsen, President and Chief Executive Officer of Bio-Path Holdings. "AML patients that fail or relapse from frontline venetoclax-based therapy have very poor prognosis with a median overall survival of less than three months. The third dosing cohort completed enrollment faster than expected, which we believe reflects the urgent need for additional treatment options. We look forward to quickly advancing this study through the fourth dosing cohort and into the combination therapy segment of this Phase 1/1b study with increased levels of BP1002 for the treatment of these vulnerable patients."

The current standard of care for patients with AML not eligible for intensive chemotherapy is venetoclax, an oral Bcl-2 inhibitor that targets the BH3 domain of the Bcl-2 protein, in combination with a hypomethylating agent or with low-dose cytarabine. However, many patients become resistant to venetoclax treatment. A published study found that AML patients who had relapsed from frontline venetoclax-based treatment were refractory to salvage therapy and had a median survival of less than 3 months. By targeting Bcl-2 at the mRNA level rather than the protein, BP1002 may overcome and prevent some of the mechanisms of resistance that affect venetoclax treatment.

The Phase 1/1b clinical trial is being conducted at several leading cancer centers in the United States, including the Weill Medical College of Cornell University, The University of Texas MD Anderson Cancer Center, Scripps Health, and The University of California at Los Angeles Cancer

Center. The approved treatment cycle is two doses per week over four weeks, resulting in eight doses administered over twenty-eight days. The Phase 1b portion of the study is expected to commence after completion of BP1002 monotherapy cohorts and will assess the safety and efficacy of BP1002 in combination with decitabine in refractory/relapsed AML patients.

Gail J. Roboz, M.D., is the National Principal Investigator for the Phase 1/1b trial. Dr. Roboz is a Professor of Medicine and Director of the Clinical and Translational Leukemia Program at the Weill Medical College of Cornell University and the New York-Presbyterian Hospital in New York City. Gary Schiller, M.D., The University of California at Los Angeles Cancer Center, Maro Ohanian, D.O., Department of Leukemia, University of Texas MD Anderson Cancer Center, and David Hermel, M.D., Scripps Health, are each serving as principal investigators.

About Bio-Path Holdings, Inc.

Bio-Path is a biotechnology company developing DNAbilize®, a novel technology that has yielded a pipeline of RNAi nanoparticle drugs that can be administered with a simple intravenous infusion. Bio-Path's lead product candidate, prexigebersen (BP1001, targeting the Grb2 protein), is in a Phase 2 study for blood cancers, and BP1001-A, a drug product modification of prexigebersen, is in a Phase 1/1b study for solid tumors. The Company's second product, BP1002, which targets the Bcl-2 protein, is being evaluated for the treatment of blood cancers and solid tumors, including acute myeloid leukemia. In addition, an IND application is expected to be filed for BP1003, a novel liposome-incorporated STAT3 antisense oligodeoxynucleotide developed by Bio-Path as a specific inhibitor of STAT3.

For more information, please visit the Company's website at http://www.biopathholdings.com.

Forward-Looking Statements

This press release contains forward-looking statements that are made pursuant to the safe harbor provisions of the federal securities laws. These statements are based on management's current expectations and accordingly are subject to uncertainty and changes in circumstances. Any express or implied statements contained in this press release that are not statements of historical fact may be deemed to be forward-looking statements. Any statements that are not historical facts contained in this release are forward-looking statements that involve risks and uncertainties, including Bio-Path's ability to raise needed additional capital on a timely basis in order for it to continue its operations, have success in the clinical development of its technologies, the timing of enrollment and release of data in such clinical studies, the accuracy of such data, limited patient populations of early-stage clinical studies and the possibility that results from later stage clinical trials with much larger patient populations may not be consistent with earlier stage clinical trials, the maintenance of intellectual property rights, that patents relating to existing or future patent applications will be issued or that any issued patents will provide meaningful protection of our drug candidates, the impact, risks and uncertainties related to global pandemics, including the COVID-19 pandemic, and actions taken by governmental authorities or others in connection therewith, and such other risks which are

identified in Bio-Path's most recent Annual Report on Form 10-K, in any subsequent quarterly reports on Form 10-Q and in other reports that Bio-Path files with the Securities and Exchange Commission from time to time. These documents are available on request from Bio-Path Holdings or at www.sec.gov. Bio-Path disclaims any intention or obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

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